

**MEMORANDUM OF UNDERSTANDING**  
**between**  
**THE FOOD AND DRUG ADMINISTRATION**  
**and**  
**DRUGS.COM**

**I. PURPOSE AND GOALS**

This Memorandum of Understanding ("MOU") establishes a cooperative public education program between two entities (individually a Party -- collectively the Parties): The Food and Drug Administration (FDA), Office of External Relations (OER), Consumer Health Information Staff and Drugs.com.

The purpose of the cooperative program is to:

- extend the reach of FDA Consumer Health Information; and
- provide consumers with better information and timely content concerning public health and safety topics, including alerts of emerging safety issues and product recalls.

**II. AUTHORITY**

This MOU is authorized pursuant to section 903 of the Food, Drug and Cosmetic Act (21 USC 393(d)(2)).

**III. BACKGROUND**

The Parties have entered into this Agreement in mutual recognition of the need to empower consumers with health information they can apply in everyday life.

The FDA Web site currently receives approximately 6 million visitors per month, most of which are representatives of regulated industry. Within the agency's site, FDA Consumer Health Information receives approximately 250,000 page views per month. Drugs.com is visited by 11 million individuals each month proactively seeking information on medications. Drugs.com's mission is to empower patients with the knowledge to better manage their own healthcare and to improve safety by assisting in the reduction of medication errors.

This MOU meets the requirements set forth in FDA's policy statement on co-branding of FDA Consumer Health Information, which is available online at <http://www.fda.gov/ForConsumers/ucm126390.htm>.

FDA and Drugs.com recognize that this partnership agreement is not intended, and may not be relied on, to create any right or benefit, substantive or procedural, enforceable by law by any party against the United States or against Drugs.com.

**IV. PROGRAM COMPONENTS AND ACTIVITIES**

The components and activities of the Program are expected to increase FDA's capacity to disseminate time-sensitive public health information. The cooperative public education program will include the following components:

- An FDA/Drugs.com joint online resource on the Drugs.com site (the "Program"), which will feature editorial and visual FDA Consumer Health Information such as videos and photo slideshows. The parties will mutually agree to the type and exact items of content made available through the Program and on other parts of Drugs.com. As a general matter, the Program

will feature a minimum of 50 articles of FDA content and provide users with access to the agency's full catalog of Consumer Updates. Drugs.com will promote the Program throughout their site and within interactive tools.

- Integration of FDA Consumer Health Information with Drugs.com's mobile phone platform, which currently receives approximately 140,000 visitors per month.

## **V. TERMS OF THE MOU**

1. FDA Consumer Health Information must be easily distinguishable from non-FDA content within the Program. Placement of FDA Consumer Health Information within the Program should be clearly identified as such. Examples of clearly identifying FDA Consumer Health Information would be placing this information in a box and/or using a distinct color to distinguish it from non-FDA content, and/or otherwise clearly distinguishing the non-FDA content via an adequate disclaimer statement.
2. Printed and online Web pages containing FDA Consumer Health Information must be free of advertisements to avoid implying FDA's endorsement or support for a particular product, service or Web site.
3. This MOU does not grant exclusivity to either party. Neither party is restricted from participating in similar initiatives with other public or private agencies, organizations or individuals.
4. All activities within the scope of this Agreement must comply with Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998 (see HHS policy on Section 508 compliance at <http://www.hhs.gov/od/508policy/index.html>); and Office of Management and Budget (OMB) policies for protecting private information (see [www.usa.gov/webcontent/regs\\_bestpractices/laws\\_regs/privacy.shtml](http://www.usa.gov/webcontent/regs_bestpractices/laws_regs/privacy.shtml)).
5. FDA and Drugs.com will cooperate in maintenance of each party's trademarks and logos. The FDA will not permit use of its logo for marketing purposes other than to promote the Program. The use of FDA names or logos shall not imply any exclusive arrangement. Any use of FDA logos must be approved, in advance, by FDA's Consumer Health Information Staff.
6. Both parties agree that information FDA provides to Drugs.com shall be public domain material. FDA shall have full rights to reuse the content for all FDA purposes, and the right to share with other collaborators or requestors.
7. Drugs.com agrees to maintain current FDA Consumer Health Information within the Site and Program. FDA Consumer Health Information must be removed from the Program in the following circumstances: (1) within 3 years of the date of its first publication; (2) upon termination of this Agreement, if the partnership Agreement terminates less than 3 years after the material is posted; (3) upon FDA's request in circumstances in which the information becomes outdated; or (4) as soon as commercially practicable but no longer than 72 hours after receipt of a written request from FDA to remove the material, regardless of reason. Drugs.com's failure to display current FDA Consumer Health Information may result in the termination of this Agreement.
8. This Agreement does not and is not intended to transfer to either party any rights in any technology or intellectual property.

## **V. LINKS**

FDA and Drugs.Com will provide inbound and outbound links to and from the Program and the FDA's Consumer Health Information Web page.

FDA will not provide Drugs.com access to any document or information to the extent that providing such access would place the FDA in breach of the Trade Secrets Act, codified at 18 U.S.C. sec. 1905; the Privacy Act, codified at 5 U.S.C. sec. 552a; the Food, Drug, and Cosmetic Act, codified at 21 U.S.C. sec. 301, et seq (particularly 21 U.S.C. sec. 331(j)); FDA regulations (21 Code of Federal Regulations (CFR)); or any other Federal law or regulation.

## **VI. LIAISON OFFICERS**

Jason Brodsky  
Director, Consumer Health Information Staff  
Office of External Relations  
U.S. Food and Drug Administration  
5600 Fishers Lane, Room 15A-29  
Rockville, Maryland 20857  
PHONE: 301-827-6251  
E-mail: [Jason.Brodsky@fda.hhs.gov](mailto:Jason.Brodsky@fda.hhs.gov)

Philip Thonton  
Chief Executive Officer  
Drugs.com  
P. O. Box 302-739  
North Harbour  
Auckland 0751  
New Zealand  
PHONE: (+64) 9-476-8500  
E-mail: [Philip.Thornton@drugs.com](mailto:Philip.Thornton@drugs.com)

Each Party shall appoint a representative who shall act as the liaisons between such party and the other party's representative. A party may update its representative upon written notice to the other party.

## **VII. LENGTH OF THE AGREEMENT AND ASSESSMENT MECHANISMS**

This MOU will be effective for three years from the date of signature by the later Party to sign it. At the end of each year, and annually thereafter, as long as the Agreement remains in force, the Parties will evaluate the effectiveness of the Agreement in meeting their goals and may amend the Agreement, continue it as written, or dissolve the Agreement by mutual consent. In addition, at any time, the Parties may modify or terminate the Agreement by mutual written consent, and either Party may terminate the Agreement at any time by means of a written notice of termination.

At least every two months, Drugs.com will provide gratuitously, and with no expectation of reimbursement, statistical information to FDA concerning the reach of the cooperative educational program. This information will include metrics on the number of users visiting the joint online resource and individual content items contained therein, as well information concerning the reach of the content integrated with Drugs.com's mobile platform. The Parties agree that Drugs.com will provide information regarding usage to the FDA. This information will be jointly reviewed. The purpose of reviewing this

information will be to evaluate the effectiveness of the collaboration and to make any necessary adjustments in approach, which may include termination of the partnership.

#### **VIII. NO COMMITMENT OF FUNDS**

Nothing in this MOU shall be construed to obligate either party to make payments to the other.

#### **IX. LIMITATIONS ON LIABILITY**

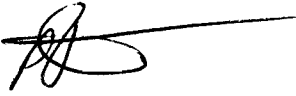
IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER ANY THEORY OF LIABILITY, HOWEVER ARISING, FOR ANY COSTS OF COVER OR FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF THIS AGREEMENT.

The provisions of this Section IX shall survive termination, cancellation or expiration of this MOU or any reason whatsoever.

#### **X. SIGNATURES OF RESPONSIBLE PARTIES**

By signing this agreement, the responsible parties agree to the terms and conditions of this MOU, and they further agree to adhere to FDA's policy statement on co-branding of FDA Consumer Health Information.

DRUGS.COM

BY:   
\_\_\_\_\_  
Signature of authorized representative

10/13/09  
Date

PHILIP THORNTON  
Chief Executive Officer  
Drugs.com

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY:   
\_\_\_\_\_  
Signature of authorized representative

7/29/09  
Date

JOSHUA M. SHARFSTEIN, M.D.  
Principal Deputy Commissioner of Food and Drugs  
Department of Health and Human Services